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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,483	08/24/2001	Fabrice Duprat	1201-CIP-DIV-2-00	3851

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IP DEPARTMENT OF PIPER RUDNICK LLP
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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT PAPER NUMBER

1632

10

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,483

Applicant(s)

DUPRAT ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

Applicant's election without traverse of Group VII, claims 29-32 in Paper No. 8 is acknowledged. It is acknowledged that claims 1-28 are cancelled with the filing of a divisional application on August 24, 2001. It is also noted that preliminary amendment dated August 24, 2001 amending claims 29 and 33 was entered July 02, 2003 in paper No. 7. in paper No. 4. It is further acknowledged that preliminary amendment was received September 29, 2001 amending claims 31 and 32 in paper No. 4.

The restriction mailed on 03/25/2003 in Paper No. 8 is vacated. A new restriction appears below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 29-31, drawn to a transgenic animal comprising a transgene comprising a nucleic acid coding for a potassium transport channel classified in class 800, subclass 8.
- II. Claim 32, drawn to a transgenic knockout animal deficient for a potassium transport channel, classified in class 800;800, subclass 8;13.
- III. Claim 33, drawn to a pharmaceutical composition for treatment of diseases comprising a nucleic acid encoding a potassium transport channel or cells comprising a vector comprising said nucleic acid, classified in class 536;424;424;435;435, subclass 23.1;93.1;93.21;252.3;325.

The inventions are distinct, each from the other because of the following reasons:
Inventions I and II are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case

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the structure of the animals is different. The animal of Group I comprises a transgene that encodes a potassium transport channel. The animal of Invention II is deficient for a potassium transport channel. The phenotype and uses for the animal of each invention is different. The animal of each invention is not necessary for the other. The animals of each invention are made through different processes requiring different method steps, reagents and technical considerations. The burden required to search the animals of each of Inventions I and II together would be undue.

The animals of Inventions I and II and the pharmaceutical of Invention III are patentably distinct. The animals of Invention I and II can be used to characterize and define the role of potassium transport channels while the nucleic acid or cells of Invention III can be used in gene therapy. The animals are not necessary for the pharmaceutical and the pharmaceutical is not necessary for the animals. The burden required to search the animals of each of Inventions I and II with the pharmaceutical of Invention III would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

PETER PARAS
PATENT EXAMINER



Valarie Bertoglio
Examiner
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